REMARKS

Reconsideration of the application as amended is requested. The claims as amended are directed to maize seeds. Support for these amendments is found throughout the application. No new matter has been added by virtue of the amendments to the claims.

Objection to the Specification

The specification has been objected to, the Examiner taking the position that data has been omitted from the table spanning pages 37-38 because units of measure are not specified. This objection is respectfully traversed.

Applicants reiterate that those of ordinary skill in the art of corn breeding and related nutritional analysis would readily understand that the measurements set forth in the table at issue refer to weight percent protein and oil, in light of the entire disclosure, convention, and the state of the art at the priority date of the present application.

At page 37, lines 20-21, just above the table at issue, the specification states that: "[t]he following provides an example of an inbred line according to the present invention." The table at issue compares protein, oil, and phytate content of wild-type lines UO95, UU01, B73, and WD22 (on page 37) with mutants UO95py, UU01py, B73lpa-1-R, and WD22py (on page 38). At page 8, lines 19-28, in relation to one embodiment of the invention, the specification states:

> [a] number of other crosses and inbreds can be employed. For example, the following female inbreds BD68py, TR306py, WD22py and TR329py were crossed with male inbreds UO95py, UU01py, UE95py, TR335py and TR386py to make high-yielding hybrid combinations. Crosses with UO95py are particularly preferred and hybrids made therefrom are specific embodiments of the present invention. The hybrid grain of the present invention [is, *sic*] characterized by having ~6% oil and 12% protein (or 3% more oil and 3% more protein than yellow dent corn) and at least about 33% reduction in phytic acid content.

Thus the specification explicitly discloses that UO95py, UU01py, and WD22py, as inbreds which can be employed as embodiments of the invention, are characterized by certain percentages of oil and protein. At page 10, lines 26-27, the specification states that: "[p]ercentages are expressed on a dry weight basis as amount of a constituent per kernel, unless described otherwise." Moreover, at page 7, lines 22-27, the specification

recites that the seed or grain of the invention has "at least about 5% by dry weight, preferably at least about 6%, alternatively at least about 7%, oil; at least 11% by dry weight, preferably at least about 12%, alternatively at least about 13%, protein. . ." Thus the person of ordinary skill would reasonably conclude that the units of the numbers set forth in the "Protein" and "Oil" columns of the table spanning pages 37 and 38, referring to inbreds described as specific embodiments of the invention, are weight percentages.

The remaining columns of the table spanning pages 37 and 38 relate to phytate content of the wild type and mutant inbred lines. The table appearing between lines 15 and 20 of page 37 also relates to phytate content of the inbred lines, and at lines 13 and 14, the specification states that phytic acid contents are measured as "mg/g of seed". The Examiner's attention is directed to the fact that the numbers appearing in the "Phytic acid" columns of the upper table are the same as those appearing in the "Phytate" column of the table spanning pages 37 and 38, for each respective inbred line. Thus the person of ordinary skill would reasonably conclude that the units for the "Phytate" column of the table spanning pages 37 and 38 are mg/g of seed.

Applicants do not believe that an amendment to the table is necessary in light of the entirety of the disclosure. However, to facilitate prosecution, the table has been amended as requested by the Examiner.

Rejection under 35 U.S.C. § 112

1. <u>Deposit</u>

Claims 1-2, 14, 17-18, 21 and 23-30 stand rejected under § 112, first paragraph, the Examiner taking the position that the specification does not provide any definitive evidence that EMS mutagenesis of maize pollen will result in mutant seed having the phenotypic characteristics of the claimed invention. The Examiner opines that the method of mutagenesis and selection set forth in the specification is not a repeatable process to obtain the exact same seed in each occurrence, and that absent a deposit, the seed claimed is not readily available to the public.

Applicants do not acquiesce in the Examiner's position regarding the reproducibility of the mutagenesis method disclosed in the application, as discussed more

fully below. However, the instant rejection is believed to have been obviated by the previous amendment to the specification indicating the ATCC accession number of the deposited strain EX1965py and the submission of a copy of the ATCC International Form indicating that EX1965py was deposited under the terms of the Budapest Treaty. Withdrawal of the "deposit" rejection of claims 1-2, 14, 17-18, 21 and 23 is therefore respectfully requested.

2. Enablement

Claims 1-2, 14, 17-18, 21 and 23 stand rejected under § 112, first paragraph, as only being enabling for the mutant corn seed UO95py. The Examiner takes the position that the specification does not provide sufficient guidance for one skilled in the art to determine how to employ EMS mutagenesis in order to reliably obtain the desired phenotype, or how to determine which EMS mutagenized seed to select for screening in order to be likely to identify the desired phenotype. This rejection is respectfully traversed.

It is settled law that a specification containing a teaching of the manner and process of making and using an invention, in terms corresponding to the scope of the claimed subject matter *must* be taken as in compliance with the enabling requirement of § 112, first paragraph *unless* there is reason to doubt the objective truth of the statements contained therein. *In re Marzocchi & Horton*, 169 USPQ 367, 369 (CCPA 1971) (*emphasis in original*). The Examiner opines that

> . . .the exemplification of a single seed line that meets the limitations of a non-lethal mutant cereal seed having at least 5% by weight oil, at least 11% by weight protein, and at least one-third reduction in phytic acid does not provide sufficient guidance for one skilled in the art to identify other seed lines that meet these limitations.

The Examiner has failed to state any evidence in support of her opinion that the mutagenesis technique taught in the instant specification is not a reproducible process.

At page 13, line 25 to page 14, line 11, the specification teaches that the grain of the invention is made by crossing oil burdened, protein laden corn plants with maize plants carrying the low phytic acid allele. At page 18, lines 9-19 the specification states that

> [t]he low phytic acid plant of the present invention can be developed by following the listed steps which do not take undue experimentation and can be done by the ordinarily skilled person in the art of plant breeding. The best method for generating a low phytic acid maize plant employs maize pollen mutagenesis. The induced mutation in a haploid pollen grain would give rise to a heterozygous genotype in the seed. Since low phytic acid presently is known as a recessive gene, the resultant mutant seed must be planted and selfed and the resultant plants seeds assayed for the mutant phenotype. The assaying of the seed should be done when the seed is in the mature stage or harvesting stage.

The EMS mutagenesis technique is taught at page 18, line 20 to page 19, line 14, and in Example 3. A rapid screening procedure for detecting low phytate seeds in mutagenized populations is taught at page 33, lines 18-26.

At page 19, line 25 to page 20, line 8, the specification teaches that the method of the invention can be used to form two inbreds which may be crossed to form a high yielding hybrid.

> [o]ne or both of the inbreds fixed for the low phytic acid can be crossed to an inbred which carries the elevated oil trait. Either inbred can cary [*sic*] the high protein trait if it was selected as an additive trait. Thus allowing the hybrid combination to carry both traits the recessive low phytic acid and the dominant or additive oil genes. A corn plant is repeatedly bred until the low phytic acid allele is present in two inbreds that cross well to one another. Likewise at least one of the inbreds in the hybrid combination must contain the oil burdened trait and/or the protein laden corn alleles.

A second method for obtaining the grain of the invention, using the method set forth in WO92/08341, is also referenced.

The specification teaches that oil burdened corn can be developed by recurrent selection, as evidenced by commercially available high oil corn. Methods for measuring the oil content of seeds were well known at the priority date of the present application, as indicated in the Declaration pursuant to 37 C.F.R. §1.132 of Jerry Weigle and Ming-Tang Chang, co-inventors of the present application ("the Declaration").

From page 15, line 29 to page 17, line 27, the specification teaches that:

- high protein corn had been developed by recurrent selection at the University of Illinois;
- high protein material was available from Wilson seeds, Crows, and from public depositories and universities

- high protein material can be generated by recurrent selection
- high protein corn can be generated by use of certain mutations such as o2:su2 which have 49% more lysine than normal hybrids but have decreased protein yields.

Methods for measuring the protein content of seeds were well known at the priority date of the present application, as indicated in the Declaration.

The specification also teaches that plants carrying the low phytic acid allele were available as experimental material, from the USDA, in the form of mutants B73 lpa1-R and A632 lpa1-R. Moreover, as indicated in U.S.Pat.No. 5,689,054 (Raboy '054), a copy of which is attached hereto as Exhibit A[1], methods for generating low phytic acid mutants were known at the priority date of the present application. Raboy '054 discloses and claims, for example:

> 1. A non-lethal, mutant seed of a cereal plant species characterized by low phytic acid expression relative to wild-type seed of said species.
>
> 10. A method for selecting for a mutation in a plant species, said mutation being responsible for low phytic acid expression in the seed of said plant comprising the steps of:
>
> a. obtaining plants which have been self-pollinated through at least one generation subsequent to mutanization [*sic*] of seed in the parentage of said plants and assaying phenotypically normal seeds from the self-pollination for an indicator of phytic acid level;
> b. comparing the phytic acid level determined in (a) with a standard value for the level of phytic acid in wild-type seed of said plant; and
> c. selecting a seed which is characterized by low phytic acid expression relative to said standard value.

At col. 4, lines 50-59 and in Example 1, Raboy '054 discloses ethyl methanesulfonate (EMS) induced mutagenesis using the method of Neuffer and Coe, *Maize for Biological Research*, ed. By W.F. Sheridan, Plant Molecular Biology Association (1982). The Examiner's attention is directed to page 18, lines 22-27 and Example 3 of the instant application which also refer to use of the Neuffer EMS mutagenesis method to generate the mutant seed of the present claims. Methods for measuring phytic acid content of plants are taught in Raboy '054 at col. 5, lines 7-32 and at col. 8, lines 29-41, and the

[1] Raboy '054 was cited in the Information Disclosure Statement filed on June 20, 2002. Exhibit A is provided for the convenience of the Examiner.

instant application teaches methods for measuring phytic acid at page 18, line 27 to page 19, line 10 and in Example 4.

Moreover, the Declaration discloses that using the methods disclosed in the specification, Applicants have made a large number of mutant inbred corn lines and hybrids falling within the scope of the present claims. The Examiner's attention is directed to the table presented in the Declaration, which discloses 14 such hybrids, representing various crosses of 9 separate mutagenic events, which are currently in pre-commercial development. Applicants note that the hybrids selected for pre-commercial development are a subset of the many hybrids and inbred lines which have been made using the methods set forth in the specification.

Applicants reiterate that the invention as claimed may be practiced by those of ordinary skill without undue experimentation, and withdrawal of the rejection of claims 1-2, 14, 17-18, 21 and 23 under § 112, paragraph 1, is respectfully requested.

In light of the amendments and arguments set forth above, Applicants submit that all of the rejections contained in the final Office Action dated October 22, 2002 have been overcome, and the application is in condition for allowance. Should the Examiner wish to discuss the application, she is invited to telephone the undersigned. If any additional fees are due with respect to this submission, authorization is hereby given to charge such fees, or to credit any overpayment, to Deposit Account No. 02-1197.

Respectfully submitted,

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